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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,747	09/22/2003	Craig M. Carpenter	NMT-013	1903

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EXAMINER	
RYCKMAN, MELISSA K	
ART UNIT	**PAPER NUMBER**
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,747	CARPENTER ET AL.	
	Examiner	Art Unit	
	Melissa Ryckman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-16,18-25 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-16,18-25,27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to arguments and amendments submitted 4/10/07, currently claims 1-12,14-16,18-25 and 27-30 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 14 recites the limitation "said front-end loader" in line 9 of claim 1 and line 10 of claim 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Barbut et al. (U.S. Patent No. 6,592,546).

Barbut teaches a method for delivering a collapsible prosthetic occluder to a patient comprising a front-end loader comprising a proximal portion comprising an expanded lumen (384), a tube having a proximal end and distal end (350) with a beveled end (Fig. 9) that receives a intracardiac device (318) in the lumen of said tube.

Said intracardiac device is delivered to the patient (Fig. 5). Said intracardiac device is implanted at the anatomical site. Said intracardiac device is received in the lumen of said tube and retrieved from the patient (Fig. 22). The device is implanted a the anatomical site of the patient (at the time it is being used the device is implanted into the walls of the aorta, 99).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-12, 14, 15,16 and 18- 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut et al. (U.S. Patent No. 6,592,546) further in view of Tsugita (U.S. Patent No. 6,168,579 B1).

Claims 1, 5, 11 and 12:

Barbut teaches an aortic occluder comprising a proximal portion comprising an expanded lumen (384) that is conically shaped (385, Fig. 9), a tube having a proximal end and distal end (350) with a beveled end (Fig. 9) that receives the intracardiac device into the lumen of the distal portion of the front-end loader (318).

The beveled end receives said prosthetic occluder (317) to withdraw (Fig. 22) or deliver (Fig. 5) said prosthetic occluder from or into a patient's body. Barbut teaches the claimed invention but does not have the device going into the lumen with the

beveled tip, however Tsugita teaches a tube (30) receives said intracardiac device (25) into the lumen of said distal portion of the front-end loader (Figs. 1A, col. 6, ll. 7). It would have been obvious to one of ordinary skill in the art to have the lumen receive the occluder as this protects the occluder during delivery to the body.

Claims 14, 18, 24 and 25:

Barbut teaches an aortic occluder comprising a proximal portion comprising an expanded lumen (384) that is conically shaped (385, Fig. 9), a tube having a proximal end and distal end (350) with a chamfered (beveled and chamfered are synonymous) end (Fig. 9) that receives a prosthetic occluder (318).

The chamfered end receives said prosthetic occluder (317) to withdraw (Fig. 22) or deliver (Fig. 5) said prosthetic occluder from or into a patient's body. Said chamfered end receives said prosthetic occluder through said distal end (Fig. 5). Barbut teaches the claimed invention but does not have the device going into the lumen with the beveled tip, however Tsugita teaches a tube (30) receives said intracardiac device (25) into the lumen of said distal portion of the front-end loader (Figs. 1A, col. 6, ll. 7). It would have been obvious to one of ordinary skill in the art to have the lumen receive the occluder as this protects the occluder during delivery to the body.

Claims 2,3, and 6-10:

Barbut does not show a chamfered end (end at 350) around the perimeter of the distal end of the tube (end at 350) however it would have been well known to one of ordinary skill in the art to include a chamfered end as this sharpens said tip in order to pierce said occluder.

Said occluder comprises an occluder for treating an atrial septal defect, ventricular septal defect, patent ductus arteriosus, and patent foramen ovale. Barbut et al. does not specifically mention these defects, however Barbut et al. teaches use in the aorta (abstract, ll. 4), this occluder would be appropriate for treating the defects mentioned above as these defects do not require an occluder different than an occluder for the aorta.

Claims 15,16, and 19-23:

Barbut does not show a beveled end (end at 350) around the perimeter of the distal end of the tube (end at 350) however it would have been obvious to one of ordinary skill in the art to include a beveled end as this sharpens said tip in order to pierce said occluder.

Said occluder comprises an occluder for treating an atrial septal defect, ventricular septal defect, patent ductus arteriosus, and patent foramen ovale. Barbut et al. does not specifically mention these defects, however Barbut et al. teaches use in the aorta (abstract, ll. 4), this occluder would be appropriate for treating the defects mentioned above as these defects do not require an occluder different than an occluder for the aorta.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut et al. (U.S. Patent No. 6,592,546) as applied to claim 27 above, further in view of Tsugita (U.S. Patent No. 6,168,579 B1).

Barbut does not specify said intracardiac device crossing a gland, however it would have been obvious to one of ordinary skill in the art to cross over a gland as said occluder of Barbut passes through vessels (abstract ll. 3) and therefore will cross over a gland, when considered from different viewpoints of its path. Barbut does not teach the occluder going into a sheath however, Tsugita teaches a tube (30) receives said intracardiac device (25) into the lumen of said distal portion of the front-end loader (Figs. 1A, col. 6, ll. 7). It would have been obvious to one of ordinary skill in the art to have the lumen receive the occluder as this protects the occluder during delivery to the body.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut et al. (U.S. Patent No. 6,592,546).

Barbut teaches a method for delivering a collapsible prosthetic occluder to a patient comprising a front-end loader comprising a proximal portion comprising an expanded lumen (384), a tube having a proximal end and distal end (350) with a beveled end (Fig. 9) that receives intracardiac device (318) in the lumen of said tube. Said intracardiac device is delivered to the patient (Fig. 5). Said intracardiac device is received in the lumen of said tube and retrieved from the patient (Fig. 22). The lumen of said proximal portion is joined to the lumen of the distal portion (Fig. 9, 350). Barbut does not specify a chamfered end at the beveled end, however it would have been well known to one of ordinary skill in the art to have a chamfered end as this would sharpened said tip to pierce said occluder.

Response to Arguments

Applicant's arguments with respect to all the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(U.S. Patent No. 5,928,246) Gorden et al. teaches a stent securing catheter.

(U.S. Pub. No. 2005/0004648) Boekstegers teaches a method for delivering a ventricular stent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571)-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER